K062754

510(k) Summary of Safety and Effectiveness

Date: September 13, 2006

Submitter: Patient Monitoring Division
Datascope Corp.

NOV - 2 2006

Contact Person: Kathleen Kramer
Supervisor, Clinical & Regulatory Affairs
Patient Monitoring Division
Datascope Corp.
Telephone: (201) 995-8169
Fax: (201) 995-8605

Device trade name: Gas Module SE

Common/usual name: Airway gas, pressure and volume, anesthetic agent and agent identification and gas exchange measurement device and airway gas and patient spirometry accessories.

Classification names: 21 CFR 868.1620 - Analyzer, Gas, Halothane, Gaseous- Phase (Anesthetic Conc.)
21 CFR 868.1850 - Spirometer, Monitoring (w/wo alarm)

Predicate Devices: K974903 Gas Module II
K001814 Datex-Ohmeda Compact Airway Module M-CAiOVX and M-COVX

Device Description: The subject device is a modified version of the Datascope Gas Module II, which was previously cleared by FDA under K974903 on March 13, 1998 and now marketed as the Gas Module SE. There have been no significant changes to the Gas Module SE since its clearance. At this time, Datascope Corp. has added a new feature to the Gas Module SE capabilities, the measurement of spirometry via a spirometry module, which is the same spirometry module residing in the Datex-Ohmeda Compact Airway Module M-CAiOVX and M-COVX (K001814).

The Gas Module SE is an independently powered unit capable of interfacing with Datascope Patient Monitors using the Datascope proprietary communications protocol.

The modified Gas Module SE measures in real-time, breath-by-breath O_2, CO_2, N_2O gases. Additionally, the Gas Module SE monitors the anesthetic agents Halothane, Isoflurane, Sevoflurane, Desflurane and Enflurane.

Intended Use: The intended use of the Gas Module SE is the monitoring of airway gases, during anesthesia and/or assisted respiration. The intended environment of use is the anesthesia department, including the Operating Room (OR) and the post anesthesia care units (PACU), etc. as summarized in the Operating Instructions. This is the same intended use as previously cleared for the Gas Module SE, K974903.

Technology: The Gas Module SE is composed of a spirometry module, a power supply and a communications interface board that enables the unit to communicate utilizing Datascope's proprietary communications protocol.

Test Summary: The results of verification tests conducted demonstrate that the functionality and performance characteristics of the Gas Module SE are comparable to the currently marketed predicate devices.

Conclusion: The results of all verification testing demonstrate that the Gas Module SE is as safe, as effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kathleen Kramer
Supervisor, Clinical & Regulatory Affairs
Datascope Corporation
Patient Monitoring Division
800 Macarthur Boulevard
Mahwah, New Jersey 07430

NOV - 2 2006

Re: K062754
Trade/Device Name: Gas Module SE
Regulation Number: 21 CFR 868.1620
Regulation Name: Halothane Gas Analyzer
Regulatory Class: II
Product Code: CBS
Dated: September 13, 2006
Received: September 14, 2006

Dear Ms. Kramer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if known): K062754

Device Name: Gas Module SE

Indications for Use:

The indications for use for the Gas Module SE include monitoring of airway gases, during anesthesia and/or assisted respiration. The intended environment of use is the anesthesia department, including the Operating Room (OR) and post anesthesia care units (PACU), etc.

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; Number: K062754

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)